

**NOT SO FAST: PROVING IMPLIED FALSE  
CERTIFICATION THEORY POST-ESCOBAR**

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## I. INTRODUCTION

The False Claims Act (“FCA”) has been around since the days of President Lincoln.<sup>1</sup> Gone are the days since the American Civil War when the Act was first dubbed Lincoln Law.<sup>2</sup> Compared to the early years of the law when it had a very limited impact, it is now the government’s leading enforcement tool to bring civil causes of action against contractors in the financial, defense, for-profit education, and the health care industry.<sup>3</sup> The lion’s share of the most significant FCA settlements comes from the health care and pharmaceutical arenas.<sup>4</sup> Crippling financial penalties can apply under the FCA in its most common application, for example, when someone knowingly presents or causes to be presented a false or fraudulent claim for payment or approval to the federal government.<sup>5</sup>

With FCA cases on the rise and penalties in the billions, circuit court precedent and the definitions of “falsity” and “materiality” have become particularly relevant in FCA jurisprudence. False claims cases can take on many different forms.<sup>6</sup> When a contractor certifies compliance with the laws, regulations, or contract terms in a claim for payment from the government, those certifications are vital. The certification informs the government, or misleads it, about the goods or services the contractor provided. It also represents compliance with the laws, regulations, and contract terms, which have a “natural tendency to influence, or be capable

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<sup>1</sup> 31 U.S.C. §§ 3729–33 (2006); *see generally* Christopher L. Martin, Jr., *Reining in Lincoln’s Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 CAL. L. REV. 227, 236-41 (2013) (detailing how the theory has developed over the years and its implications).

<sup>2</sup> Patricia Meador, *The False Claims Act: A Civil War Relic Evolves into A Modern Weapon*, 65 TENN. L. REV. 455, 483 (1998) (stating that, in the late nineties and now, it is used increasingly in the health care sphere in an effort to combat fraud, and that the health care industry faces a significant threat by the stiff penalties and damage provisions found in the False Claims Act) (explaining how the FCA is no longer a “relic of the civil war”).

<sup>3</sup> By 2014, hundreds of former pharmaceutical sales reps turned whistleblowers filed cases against manufacturers for off-label promotion of their drugs. *See Mikes v. Straus*, 274 F.3d 687, 692 (2d Cir. 2001); *see also Chesbrough v. VPA*, P.C., 655 F.3d 461, 467 (6th Cir. 2011) (“The FCA reaches claims submitted by health-care providers to Medicare and Medicaid—indeed, one of its primary uses has been to combat fraud in the health-care field.”).

<sup>4</sup> Press Release, U.S. Dep’t. of Justice, Justice Department Recovers Over \$4.7 Billion From False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016), <https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016>.

<sup>5</sup> § 3729(a)(1)(A); *see also* Martin, *supra* note 1, at 234 (explaining how this section of the FCA is the most litigated).

<sup>6</sup> S. Rep. No. 99-345, at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (“A false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation.”) (emphasis added).

of influencing” the government’s payment decision.<sup>7</sup>

When it comes to implied false certifications under the FCA, there are two kinds: express and implied.<sup>8</sup> An express false certification occurs when a contractor expressly certified that it was compliant with a law, contract term, or regulation in a claim for federal funds from the government.<sup>9</sup> An implied false certification fails to disclose in a request for payment noncompliance with material legal requirements in the statutes, regulations, or contract, thereby rendering the claim a misrepresentation and “false or fraudulent” under § 3729(a)(1)(A).<sup>10</sup> Before the highly-anticipated and unanimous Supreme Court decision in *United Health Servs., Inc. v. United States ex rel. Escobar*, the federal circuit courts were sharply divided on implied false certification theory, when to apply it, and which standard to apply.<sup>11</sup>

Manufacturers, providers, and others in the health care industry that submit reimbursements for federal funds faced greater risk during the split in authority in the appellate courts depending on where the government or *qui tam* relators filed. Then, on June 16, 2016, the Supreme Court in *Escobar* resolved the circuit split.<sup>12</sup> The future of FCA cases based on an implied false certification theory rested on the *Escobar* decision. It was the Court’s opportunity to send a death knell to implied false certification theory, but instead, it kept it alive. Universal Health lost handily. The *Escobar* Court remanded the case to the First Circuit to determine whether the noncompliance was material under the Court’s newly articulated standard.<sup>13</sup> The *Escobar* Court also held that implied certification theory could be a basis for liability where *at least* two conditions are met: (1) the claim for payment makes specific representations about the goods or services provided; and (2) the party’s

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<sup>7</sup> § 3729(b)(4).

<sup>8</sup> *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 635 (4th Cir. 2015) (“The use of ‘judicially created formal categories’ for false claims is of ‘relatively recent vintage,’ and rigid use of such labels can ‘do more to obscure than clarify’ the scope of the FCA.”) (citing *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 385 (1st Cir. 2011)).

<sup>9</sup> *United States ex rel. Wilkins v. United Health Grp.*, 659 F.3d 295, 305 (3d Cir. 2011); *see* § 3729(a)(2) (stating when express certification occurs as a result of a false *statement* made in order to receive payment for a false claim).

<sup>10</sup> *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016).

<sup>11</sup> *See* Martin, *supra* note 1, at 241 (outlining the four positions held by the various circuits); *see also* Steven M. Kaufman, *Navigating the Circuit Split on Implied False Certification*, LAW360 (Nov. 16, 2015), <https://www.law360.com/articles/719758/navigating-the-circuit-split-on-implied-false-certification>.

<sup>12</sup> *Escobar*, 136 S. Ct. at 1989 (discussing the need for the Court to grant certiorari to resolve the disagreement among the Courts of Appeals over the validity and scope of the implied false certification theory of liability).

<sup>13</sup> *Id.* at 2004.

failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.<sup>14</sup> The court focused on the requirement that the alleged falsity be “material” to the government’s decision to pay the claim and urged lower courts to limit the reach of implied certification “through strict enforcement of the Act’s materiality and scienter requirements.”<sup>15</sup> The First Circuit found that the false certifications submitted by Universal Health, which falsely represented compliance with Medicare’s regulations governing the treating professionals’ qualifications and licensing requirements, were material to the government’s decision to pay.<sup>16</sup> Universal Health lost, but future *qui tam* cases brought under the theory may be harder to prove as courts are heeding the *Escobar* mandate that the materiality test be “rigorous” and “demanding.”<sup>17</sup>

This note takes the position that the winner of *Escobar* is yet to be determined. So far, both defendants and relators are seeing positive signs in the courts’ enforcement of *Escobar*’s materiality standard. It is arguable that *Escobar*’s expansive litigation for putative false-claim cases in the health care industry could ensure relators survive summary judgment if they are able to allege sufficient facts during the pleading stage. It is plausible that defendants will have more motivation to settle FCA cases out of concern over substantial discovery requests and costly litigation. Conversely, by federal courts enforcing *Escobar*’s “demanding” materiality standard, some defendants have found fertile ground for showing that relators have not made plausible claims with particularity on how the alleged conduct rises to the level of materiality.<sup>18</sup>

Part II of this note will discuss the evolution of the theory, the rise of FCA cases and the motivation behind that rise over the past five decades, and why false implied certification theory became the most litigated provision of the Act. Part III will look at the pre-*Escobar* circuit split and the various positions taken by the courts during this period. Part IV will discuss *Escobar* and the materiality standard emphasized by the Supreme Court. Part V will evaluate what effect, if any, *Escobar*’s materiality standard would have on pre-*Escobar* decisions and whether *Escobar* makes it more or less difficult for relators to bring dismissal-proof complaints. Part V will also review the wide range in interpretation

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<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at 1994.

<sup>16</sup> United States ex rel. *Escobar v. Universal Health Servs.*, 842 F.3d 103, 111 (1st Cir. 2016).

<sup>17</sup> *Escobar*, 136 S. Ct. at 2003.

<sup>18</sup> See United States ex rel. *Kelly v. Serco, Inc.*, 846 F.3d 325, 334 (9th Cir. 2017) (explaining the alleged billing failures were not material in light of the government’s acceptance of the reports).

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of “materiality” in the federal circuit courts.

While the Supreme Court provided examples of material violations, because the tests must be conducted on a case-by-case basis, the post-*Escobar* landscape has already splintered in different directions in the definition of “specific misrepresentation” and as to which factors carry the most weight in determining whether the half-truth affected the government’s decision-making process.

## II. THE THEORY AND THE MONEY

FCA civil claims resulted in \$26.4 billion in judgments and settlements for the Treasury since 2009, with half of that figure recovered in 2015 alone.<sup>19</sup> Concerned industry stakeholders scrambled to adjust to stringent legislation and its steep penalties, while taxpayers feared that fraud and abuse in the health care industry would continue to drive up drug costs to the detriment of elderly and low-income populations. The money collected in these settlements and judgments are, in part, made possible by the Act’s *qui tam* provision, which allows cases to be filed by whistleblowers. The government can step into such cases, or, if pursued solely by the relators, the whistleblowers are eligible for approximately twenty-five to thirty percent of the recovery.<sup>20</sup> The pressure is mounting on industry stakeholders largely because entities must spend more time than ever before to ensure that they have the necessary safeguards in place to prevent crippling settlements and judgments.<sup>21</sup> Business leaders find themselves appealing to their boards of directors to invest in compliance and data mining programs and auditing personnel in order to establish risk management as a top priority.<sup>22</sup>

### A. Motivation behind the Rise

The intent, or scienter, requirement behind the Act distinguishes it from other antifraud statutes like the Stark Law, a strict liability federal

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<sup>19</sup> Press Release, U.S. Dep’t of Justice, Justice Department Recovers over \$3.5 Billion From False Claims Act Cases in Fiscal Year 2015 (Dec. 3, 2015), <https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015>.

<sup>20</sup> 31 U.S.C.A. § 3730(d)(2) (Westlaw through P.L. 115-61).

<sup>21</sup> See *United States ex rel. Lam v. Tenet Healthcare Corp* 481 F. Supp. 2d 689, 689 (W.D. Tex. 2007).

<sup>22</sup> OFFICE OF INSPECTOR GEN. OF THE U.S. DEP’T OF HEALTH AND HUMAN SERVS. & AM. HEALTH LAWYERS ASS’N, GUIDE TO CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS, <https://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRscGuide.pdf> (last visited Dec. 27, 2017) (“However, once presented (through the compliance program or otherwise) with information that causes (or should cause) concerns to be aroused, the director is then obligated to make further inquiry until such time as his/her concerns are satisfactorily addressed and favorably resolved.”).

law.<sup>23</sup> Even more powerful than Stark, the FCA is one of the strongest antifraud statutes.<sup>24</sup> Before the 1963 amendment, the *qui tam* provisions of the FCA were essentially emasculated as the relators were considered interferences with enforcement discretion.<sup>25</sup> Yet, last year, \$2.8 billion of the \$3.5 billion recovered was a result of cases brought by *qui tam* relators.<sup>26</sup> Whistleblowers are incentivized to bring suit against government contractors.<sup>27</sup> By the mid-1990s, health care fraud was second to violent crime in terms of important initiatives pursued by the attorney general.<sup>28</sup>

### B. The Theory

A contractor who, in a request for payment, fails to disclose noncompliance with material legal requirements of a statute, regulation, or contract can be subjected to an FCA cause of action pursuant to the implied false certification theory.<sup>29</sup> The failure to disclose material violations is a misrepresentation, which renders the claim false.<sup>30</sup> False claims are broadly defined under the FCA. A legally false FCA claim,

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<sup>23</sup> 42 U.S.C. § 1395nn (Westlaw through P.L. 115-61); *see also* U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., 675 F.3d 394, 396 (4th Cir. 2012); *see also* Lisa Schencker, \$237 Million Tuomey Judgment Upheld by Federal Appeals Court, MODERNHEALTHCARE.COM (July 2, 2015), <http://www.modernhealthcare.com/article/20150702/NEWS/150709975> (“It seems as if, even for well-intentioned health care providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act.”).

<sup>24</sup> *See* S. REP. NO. 99-345, at 4 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5269 (commenting that the False Claims Act is one of the more effective ways to combat).

<sup>25</sup> If the government chooses not to intervene, the relator can proceed with the action providing the court can permit the government to intervene later. *See* Martin, *supra* note 1, at 237. In light of this sentiment, Congress amended the Act in 1943 to thwart *qui tam* actions by creating a government-knowledge bar. This meant *qui tam* relators could not bring suit if the federal government already knew of the violation and the amendments decreased the payout to relators. *See* United States ex rel. Franklin v. Parke-Davis, No. CIV.A. 96-11651PBS, 2003 WL 22048255, at \*19-20 (D. Mass. Aug. 22, 2003). Relators are private persons who can bring suit in the name of the government. The court failed to consider the issue, however, because it was raised by the government, and the government had not intervened as a party in the case.

<sup>26</sup> Press Release, U.S. Dep’t of Justice, Justice Department Recovers over \$3.5 Billion From False Claims Act Cases in Fiscal Year 2015 (Dec. 3, 2015), <https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015>.

<sup>27</sup> Stuart F. Delery, Acting Assistant Attorney Gen., Dep’t of Justice, Speech at the American Bar Association’s Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement (June 7, 2012), <http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1206071.html>.

<sup>28</sup> Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 134 (2001).

<sup>29</sup> *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016).

<sup>30</sup> *Id.*

either express or implied, is based on a “false certification” theory of liability.<sup>31</sup> Federal appellate courts have generally recognized false certification theory, with false implied certification being one way for the government to prove falsity.

Implied false certification theory of liability is predicated on “the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.”<sup>32</sup>

A payment request is treated as an implied certification of compliance with the relevant statutes, regulations, and contract requirements in the absence of an express certification.<sup>33</sup> Implied false certification theory is not supported by evidence that the claimant made an express false statement.<sup>34</sup> Each time a claimant requests payment of funds and fails to disclose material contractual, statutory, and regulatory violations, liability can attach even though they did not make any affirmative misstatements.<sup>35</sup> If the certification in question is knowingly false when made, it does not matter whether it is an assertion or omission—they impliedly, falsely certified compliance with the underlying conditions of payment.<sup>36</sup> Implied false certification is significantly more expansive than express certification and has caused uncertainty among interested stakeholders for the past twenty years over when the theory could serve as a basis for liability under the False Claims Act.<sup>37</sup>

### III. THE THEORY AND ITS CASES PRE-*ESCOBAR*

Courts generally followed either a narrow application of the implied false certification theory, which was established by the Second Circuit in *Mikes v. Straus* and permitted the theory to attach only where the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid; or a

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<sup>31</sup> See Martin, *supra* at note 1, at 244.

<sup>32</sup> *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) *abrogated by* Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989, 1989 (2016).

<sup>33</sup> U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011).

<sup>34</sup> *Id.* at 239.

<sup>35</sup> Ebeid v. Lungwitz, 616 F.3d 993, 996-97 (9th Cir. 2010).

<sup>36</sup> *Id.*

<sup>37</sup> U.S. ex rel. Wilkins, 659 F.3d 295 at 305 (“There is a more expansive version of the express false certification theory called ‘implied false certification’ liability which attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment. Thus, an implied false certification theory of liability is premised ‘on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.’”) (citing *Mikes*, 274 F.3d at 699).

broader rule, developed by the First Circuit in *United States ex rel. Hutcheson v. Blackstone Medical*, which finds liability regardless of whether the condition for payment is expressly stated.<sup>38</sup> The *Mikes* court rejected the relator's claims because compliance with the cited Medicare condition was not *expressly* stated in the statute as a condition of payment.<sup>39</sup> However, in *Blackstone*, the court concluded that the language of the False Claims Act wholly failed to support the express condition-of-payment requirement that the Second Circuit established in *Mikes*.

A. "Express Condition of Payment" Position by *Mikes* Court

Of the courts that have upheld liability under the implied false certification theory, *Mikes v. Straus* is the seminal "express condition of payment" requirement case.<sup>40</sup> When the defendant physicians in a partnership that specialized in oncology fired their board-certified pulmonologist, they claimed they did so because she had trouble securing privileges in surrounding hospitals.<sup>41</sup> The pulmonologist-turned-relator, Dr. Patricia Mikes, claimed in her *qui tam* filing against the defendants that she was fired after she questioned the medical practices of the defendants—specifically, Mikes alleged the defendant physicians' operation of the spirometry tests failed to meet guidelines set forth by the American Thoracic Society.<sup>42</sup> She alleged that they employed unskilled assistants in the administration of spirometry testing and produced false data.<sup>43</sup> Because of the administration's failure to properly calibrate the spirometer daily, Mikes insisted the defendants submitted claims based on HCFA-1500 forms for the spirometry tests that did not comply with ATS guidelines.<sup>44</sup> As a result, Mikes argued the defendants made an implied false certification.<sup>45</sup> Mikes rested her assertion on the qualitative standard of care mandate of the Social Security Act.<sup>46</sup>

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<sup>38</sup> *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) *abrogated by* *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1989 (2016); *cf.* *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385 (1st Cir. 2011).

<sup>39</sup> *Mikes*, 274 F.3d at 702 ("Since § 1320c-5(a) does not expressly condition *payment* on compliance with its terms, defendants' certifications on the HCFA-1500 forms are not legally false. Consequently, defendants did not submit impliedly false claims by requesting reimbursement for spirometry tests that allegedly were not performed according to the recognized standards of health care.").

<sup>40</sup> *Mikes* introduced the express condition of payment standard. *Id.* at 697.

<sup>41</sup> *Id.* at 692.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at 693.

<sup>44</sup> *Id.* at 694-95.

<sup>45</sup> *Mikes*, 274 F.3d at 701.

<sup>46</sup> *Id.* at 694.

The *Mikes* court disagreed with the relator and refused to apply the theory because the compliance was not expressly stated in the statute as a condition of payment.<sup>47</sup> The court pointed to the section of the Medicare statute, which established conditions of participation.<sup>48</sup> This section is concerned with the quality of the care and the service that “will be of a quality which meets professionally recognized standards of health care.”<sup>49</sup> Noncompliance with this section is a violation of conditions of participation, not a condition for reimbursement.<sup>50</sup> A separate section governed the medical necessity of a given procedure and its quality.<sup>51</sup> This section contains an express condition of payment that requires “no payment may be made” unless a particular item or service be “reasonable and necessary.”<sup>52</sup> The court decided that the defendants’ performance of the spirometry tests and the submission of the HCFA-1500 form did not point to “medical necessity.”<sup>53</sup> Nor is the submission of the forms an attestation of the providers’ compliance with both of those provisions.<sup>54</sup>

Instead, the court stated that the “requirement that a service be reasonable and necessary generally pertains to the selection of the particular procedure and not to its performance.”<sup>55</sup> The court’s reasoning was, in part, an affirmation of the court’s anxiety about the FCA being used in a way that encroaches on principles enshrined by federalism and safety interests controlled by local governments.<sup>56</sup> The Third, Sixth, and

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<sup>47</sup> *Id.* at 702 (“Since § 1320c-5(a) does not expressly condition *payment* on compliance with its terms, defendants’ certifications on the HCFA-1500 forms are not legally false. Consequently, defendants did not submit impliedly false claims by requesting reimbursement for spirometry tests that allegedly were not performed according to the recognized standards of health care.”).

<sup>48</sup> *Id.* at 701-02 (The structure of the statute further informs us that § 1320c-5(a) establishes conditions of participation, rather than prerequisites to receiving reimbursement.). “[§ 1395y(a)(1)(A)] contains an express condition of payment—that is, ‘no payment may be made’—it explicitly links each Medicare *payment* to the requirement that the particular item or service be “reasonable and necessary.” *Id.* at 700.

<sup>49</sup> *Id.* at 700-01.

<sup>50</sup> The court viewed 1320c-5(a) as a prospective mandate for a provider determining eligibility to participate in the Medicare program. *Id.* at 701 (explaining § 1320c-5(a) provides that it shall be the obligation of the practitioner who provides a medical service for which payment may be made to assure compliance).

<sup>51</sup> *Mikes*, 274 F.3d at 701.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.* at 700.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 699 (“Moreover, a limited application of implied certification in the health care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the federal government play in assuring that appropriate standards of medical care are met. Interests of federalism counsel that ‘the regulation of

Tenth Circuits followed the *Mikes* court.<sup>57</sup>

*B. “Material to the Government’s Decision to Pay” Position by Blackstone Court*

In a marked turn away from the Second Circuit’s decision in *Mikes*, the First Circuit established the “material to the government’s decision to pay” standard.<sup>58</sup> When the First Circuit decided *Blackstone*, the Supreme Court had not decided the question of whether a condition must be expressly stated in order for a claim to be actionable.<sup>59</sup> The First Circuit looked to the intent of the FCA in rejecting the *Mikes* court’s position.<sup>60</sup>

In *Blackstone*, the relator, a former employee of a medical device manufacturer, filed a *qui tam* action alleging that Blackstone violated the Anti-Kickback Statute (“AKS”) by inducing physicians to use its medical devices in spinal surgeries.<sup>61</sup> The relator also argued that the defendant knowingly caused physicians and hospitals to present payment claims that included material misrepresentations.<sup>62</sup> The cost reports that the hospitals had submitted certified compliance with “the laws and regulations regarding the provisions of health care services[.]”<sup>63</sup> The innocent third parties, in this case, the hospitals, but not doctors, were required to submit a Provider Agreement and Hospital Cost Report certifying their compliance with Medicare law.<sup>64</sup> Additionally, to establish eligibility to receive reimbursement from Medicare, the hospitals were required to submit a Hospital Cost Report along with their claims for reimbursement.<sup>65</sup> On appeal, the First Circuit found that the

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health and safety matters is primarily, and historically, a matter of local concern.” (citing *Hillsborough Cty. v. Automated Med. Labs.*, 471 U.S. 707, 719 (1985)).

<sup>57</sup> See Martin, *supra* note 1, at 245.

<sup>58</sup> U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 381-82 (1st Cir. 2011).

<sup>59</sup> *Id.* at 387 (“Neither party argues that this court or the Supreme Court has expressly spoken to whether a precondition of payment must be explicitly stated in a statute or regulation to give rise to a false or fraudulent claim.”).

<sup>60</sup> *Id.* (“[T]he text of the FCA does not exhibit an intent to limit liability in this fashion.”).

<sup>61</sup> *Id.* at 379-81.

<sup>62</sup> *Id.* at 378.

<sup>63</sup> *Id.* at 381-82 (“Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report [were] provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result. The signatory of the Hospital Cost Report must certify . . . I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.”).

<sup>64</sup> *Blackstone Med., Inc.*, 647 F.3d at 381.

<sup>65</sup> *Id.* at 381.

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lower court erred in applying the express condition of payment standard.<sup>66</sup>

The First Circuit dispensed with “judicially created categories” of express or implied certification.<sup>67</sup> The court held that compliance with the AKS was an “implied condition of payment,” and, therefore, when the defendants submitted the claims for payment, they made a material misrepresentation that such condition had been met.<sup>68</sup> The defendant knowingly caused the hospital to make a false representation that was material to the government’s decision to pay regardless of whether the provision was an express condition of payment.<sup>69</sup> Pointedly, the relator was able to sufficiently allege that the hospital’s and the physician’s misrepresentation was material because the court could not conclude, as a matter of law, that the noncompliance was incapable of influencing Medicare’s decision whether or not to pay the claims.<sup>70</sup> The Fourth Circuit followed the *Blackstone* court’s “material to the government’s decision to pay” standard.<sup>71</sup>

Similar to *Mikes*, in *United States v. Sci. Apps. Int’l Corp.*, noncompliance was not a stated prerequisite to payment.<sup>72</sup> Despite the condition not being expressly stated, the D.C. Circuit broadly interpreted the standard by finding the implied certification claim actionable “*even if the contract does not specify*” that compliance with the contract term is a condition of payment.<sup>73</sup>

### C. Conditions of Participation Position

The Federal Court of Claims was the first to recognize the false

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<sup>66</sup> *Id.* at 379-80.

<sup>67</sup> *Id.* at 385-86. (“Judicially-created categories sometimes can . . . create artificial barriers that obscure and distort those requirements. The text of the FCA does not refer to ‘factually false’ or ‘legally false’ claims, nor does it refer to ‘express certification’ or ‘implied certification.’ Indeed, it does not refer to ‘certification’ at all. In light of this, and our view that these categories may do more to obscure than clarify the issues before us, we do not employ them here.”).

<sup>68</sup> *Id.* at 393-94.

<sup>69</sup> *Id.* at 379-80.

<sup>70</sup> *Blackstone Med., Inc.*, 647 F.3d at 394.

<sup>71</sup> *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 637 n.5 (rejecting the defendants’ (Triple Canopy) reliance on express conditions of payment standard from the *Mikes* court).

<sup>72</sup> *United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010).

<sup>73</sup> *Id.* (“Establish[ing] the existence of a ‘false or fraudulent’ claim on the basis of implied certification of a contractual condition, the FCA plaintiff . . . must show that the contractor withheld information about its noncompliance with material contractual requirements. . . . The “non-compliance with contract terms may give rise to false or fraudulent claims, *even if the contract does not specify* that compliance with the contract term is a condition of payment.”) (emphasis added)).

implied certification theory in 1994.<sup>74</sup> In *Ab-Tech Constr., Inc. v. United States*, the court held progress payment vouchers submitted by Ab-Tech to the Small Business Administration (“SBA”) for reimbursement were fraudulent, because, “by deliberately withholding from SBA knowledge of the prohibited contract arrangement with Pyramid, Ab-Tech not only dishonored the terms of its agreement with that agency but, more importantly, caused the Government to pay out funds in the mistaken belief that it was furthering the aims of the 8(a) program.”<sup>75</sup> The government was “duped by Ab-Tech’s active concealment of a fact vital to the integrity of that program” and the noncompliance was material to the government payment decision-making process. The court found this to be the “essence of a false claim.”<sup>76</sup> But strikingly, the payment vouchers “represented an implied certification by Ab-Tech of its continuing adherence to the requirements for participation in the [minority contractor] program,” and not an expressly stated condition for payment.<sup>77</sup>

The Eleventh Circuit’s pre-*Escobar* decision, which greatly departed from even the most liberal positions held by the First Circuit, D.C. Circuit, and Federal Circuit, applied the theory to violations of conditions of participation and sent a signal to manufacturers and providers that noncompliance with the conditions of participation in federal programs may give rise to an FCA claim—at least in the Eleventh Circuit.<sup>78</sup> The decision drew strong criticism, as it greatly expanded the false implied certification theory and, as a result, burdened the courts.<sup>79</sup>

The Sixth Circuit refused to follow the 11th Circuit’s conditions-of-participation position, and instead followed the Second Circuit’s *Mikes*

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<sup>74</sup> See Martin, *supra* note 1, at 240.

<sup>75</sup> *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 434 (1994).

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (2005) (“When a violator of government regulations is *ineligible to participate* in a government program and that violator persists in presenting claims for payment that the violator knows the government does not owe, that violator is liable, under the Act, for its submission of those false claims.”) (emphasis added).

<sup>79</sup> *United States ex rel. Conner v. Salina Reg’l Health Ctr. Inc.*, 543 F.3d 1211, 1219 (10th Cir. 2008) (“[I]f merely signing this form converts a condition of participation into a condition of payment, then every hospice provider not fully complying with all conditions of participation may be held liable under the FCA, thus undermining the distinction between conditions of payment and participation, as well as Medicare’s internal administrative structure to deal with violations of conditions of participation. To so hold would burden federal courts with what should be administrative determinations of whether medical services were performed in compliance with Medicare statutes and regulations governing participation.”).

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decision.<sup>80</sup> In *United States ex rel. Chesbrough v. VPA*, the court disagreed with relators who alleged that the provider's radiology studies and practices were defective and that the defendant, Visiting Physicians Association, P.C., subsequently defrauded the government by submitting claims for Medicare and Medicaid reimbursement.<sup>81</sup> Specifically, the relators alleged that the "studies reviewed . . . were of either no diagnostic value or limited diagnostic value."<sup>82</sup> The Sixth Circuit held that, because the allegations related to the provider's noncompliance with testing standards and not to the prerequisites to payment of claims, it was not actionable under the false implied certification theory.<sup>83</sup>

The Eleventh Circuit's opinion created even more opportunity for varying interpretations of falsity and what it meant to submit a material misrepresentation. This decision made it inevitable that the Supreme Court would intervene to resolve the split.

#### IV. ESCOBAR AND THE THEORY

##### A. *Escobar*

Yarushka Rivera was a patient with Arbour Counseling Services, a subsidiary of petitioner Universal Health Services, Inc.<sup>84</sup> Universal Health sought reimbursement using payment codes for specific counseling services.<sup>85</sup> But, in fact, Arbour had employed approximately twenty-three unlicensed staff to provide mental health services and to prescribe drugs without supervision.<sup>86</sup> Rivera died after an adverse reaction to medication prescribed by an unlicensed staff member at Arbour.<sup>87</sup> Her parents filed a *qui tam* suit under the implied false certification theory of liability, alleging that Universal Health had violated the FCA.<sup>88</sup> Rivera's parents alleged Arbour's noncompliance with staff and licensing requirements for those who treated Rivera clearly

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<sup>80</sup> *United States ex rel. Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (2011) (explaining that noncompliance with a regulation constitutes actionable fraud only when compliance is a *prerequisite to obtaining payment*). *Cf. Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) (holding that implied false certification is appropriately applied *only* when the underlying statute or regulation, upon which the plaintiff relies, *expressly* states that the provider must comply in order to be paid).

<sup>81</sup> *Chesbrough*, 655 F.3d at 464.

<sup>82</sup> *Id.* at 465.

<sup>83</sup> *Id.* at 468.

<sup>84</sup> *Id.* at 1993; *United States ex rel. Escobar v. Univ. Health Servs.*, 136 S.Ct. 1989, 1993 (2016).

<sup>85</sup> *Id.* at 1993-94.

<sup>86</sup> *Id.* at 1997.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

violated Massachusetts Medicaid regulations.<sup>89</sup> They even alleged that Universal Health had used National Provider Identification numbers matched to specific job titles for their unlicensed staff.<sup>90</sup>

The First Circuit held that every submission of a claim implicitly represents an agreement to comply with relevant regulations, and “any undisclosed violation of a precondition of payment (whether or not expressly identified as such) renders a claim ‘false or fraudulent.’”<sup>91</sup> The court said the regulations themselves proved that “compliance was a material condition of payment because the regulations expressly required facilities to adequately supervise staff as a condition of payment.”<sup>92</sup> But, the Supreme Court in *Escobar* found that the First Circuit erred in adopting the government’s expansive view that any statutory, regulatory, or contractual violation was material, so long as the defendant knew that the government would be entitled to refuse payment if it was aware of the violation.<sup>93</sup> The Court stated:

If the Government contracts for health services and adds a requirement that contractors buy American-made staplers, anyone who submits a claim for those services but fails to disclose its use of foreign staplers violates the False Claims Act. To the Government, liability would attach if the defendant’s use of foreign staplers would entitle the Government not to pay the claim in whole or part—irrespective of whether the Government routinely pays claims despite knowing that foreign staplers were used. Likewise, if the Government required contractors to aver their compliance with the entire U. S. Code and Code of Federal Regulations, then under this view failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability.<sup>94</sup>

The Supreme Court did, however, uphold the implied false certification theory, finding that it can be a basis for liability under the FCA when a contractor makes “specific representations about the goods or services provided” and when a “failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.”<sup>95</sup> The Court recognized that the subjective standard is “demanding” of the lower courts, requiring them to ask the fact-finder to determine if the government would have paid the claim if it was aware of the contractor’s noncompliance, and whether the

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<sup>89</sup> *Id.* at 1997-98.

<sup>90</sup> *Escobar*, 136 S. Ct. at 1994.

<sup>91</sup> *Id.* at 1993.

<sup>92</sup> *Id.*

<sup>93</sup> *Id.* at 2004.

<sup>94</sup> *Id.* at 2004.

<sup>95</sup> *Id.* at 2001.

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contractor itself was aware that its noncompliance was material to the government's decision in the payment-making process.<sup>96</sup>

The contractor has a duty to disclose the violation.<sup>97</sup> Defendants Universal Health, argued that the submission of a claim involves no representations, and that the "nondisclosure of legal violations is not actionable absent a special "duty of reasonable care to disclose the matter in question."<sup>98</sup> The Supreme Court disagreed. It reasoned that when Universal Health used payment codes that did not match the corresponding counseling services actually provided, or the correct credentialing held by the mental health facility staff, this constituted a misrepresentation to which the theory may apply.<sup>99</sup> In recognizing that the standard would be "rigorous" and "demanding," plaintiffs were put on notice that material misrepresentation will be adjudicated on a case-by-case basis.<sup>100</sup> It is not enough to establish materiality by showing that the government would have had the option of denying payment for the claim had it known of the noncompliance.<sup>101</sup>

The Court remanded the case for a determination on whether the mental health facility requirements were "so central" to Medicaid that, had they known of the violation, they would not have paid for their services.<sup>102</sup> Given its prior position on the implied false certification theory, it is no surprise that, on remand, the First Circuit had little trouble holding that Universal Health Services' noncompliance was sufficiently material to survive UHS's motion to dismiss.<sup>103</sup>

### B. The Materiality Factors

The *Escobar* Court utilized the "expressly stated condition" test from the Second Circuit to establish materiality, but ultimately was not persuaded.<sup>104</sup> The Court found that the FCA did not textually support the

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<sup>96</sup> *Escobar*, 136 S. Ct. at 2003.

<sup>97</sup> *Id.* at 2000 ("Likewise, an applicant for an adjunct position at a local college makes an actionable misrepresentation when his resume lists prior jobs and then retirement, but fails to disclose that his 'retirement' was a prison stint for perpetrating a \$12 million bank fraud.") (citing *Sarvis v. Vermont State Colleges*, 172 Vt. 76, 78, 80-82 (2001)).

<sup>98</sup> *Id.*

<sup>99</sup> *Id.* at 2000-01.

<sup>100</sup> *Id.* at 2002.

<sup>101</sup> *Id.* at 2003.

<sup>102</sup> The complaint only alleged that the government would not have paid Defendants' claims had they known of Defendants' fraudulent conduct. *Escobar*, 136 S. Ct. 1989 at 2004. The Court explained that the government needed to detail why it would have denied payment. *Id.*

<sup>103</sup> *U.S. ex rel. Escobar v. Univ. Health Servs.*, 842 F.3d 103, 111 (1st Cir. 2016).

<sup>104</sup> *Escobar*, 136 S. Ct. at 1996 ("What matters is not the label that the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that

express-condition designation.<sup>105</sup> Also, the Court did not consider the limitation a part of the Common Law meaning of fraud.<sup>106</sup> Instead, the Court used the First Circuit's reading of the Act by "conclud[ing] that the Act [did] not impose this limit on liability."<sup>107</sup> Identifying a provision as a condition of payment is relevant, but not automatically dispositive of materiality.<sup>108</sup>

Under *Escobar*, the government and relators must meet both the objective and subjective standards when judging if a misrepresentation was material to the decision to its pay.<sup>109</sup> Evidence that shows that a defendant knows that the government routinely denies payment based on noncompliance with the particular requirement can be used to establish subjective materiality.<sup>110</sup>

Additionally, the "government knowledge defense" can be employed by defendants, which may be crucial to the materiality bar if used in a case where the government pays a particular claim when it knows that certain requirements were violated.<sup>111</sup> The defense may also be useful if the government regularly pays a particular type of claim despite actual knowledge that a requirement was violated and "has signaled no change in position."<sup>112</sup> In that case, the government would need to show that, while it may have previously paid for a particular type of claim, it stopped payment of such claims.<sup>113</sup>

Not only will materiality depend on subjective inquiries, but also an objective test that examines if a reasonable actor in the government's position would consider the representation important in the decision-making process, or if the defendant knew the government would consider the representation significant in deciding whether to reimburse, even if a reasonable person would not consider it important.<sup>114</sup> Lastly, if the

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the defendant knows is material to the Government's payment decision.").

<sup>105</sup> *Id.* at 2001.

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at 2003.

<sup>109</sup> *Id.* at 2002-03.

<sup>110</sup> *Escobar*, 136 S. Ct. at 2003.

<sup>111</sup> *Id.* at 2003.

<sup>112</sup> *Id.* at 2003-2004. In the post-*Escobar* case, *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017), the DCAA investigated the relators' allegations and continued to pay the defendants for their services and the court, therefore, determined that the claims were not material to the government.

<sup>113</sup> *Id.* at 2003-04 ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.").

<sup>114</sup> *Id.* at 2002-03 ("[I]f a reasonable man would attach importance to [it] in determining his choice of action in the transaction'; or (2) if the defendant knew or had reason to know

misrepresentation goes to the “essence of the bargain,” then this factor can be considered material to the payment decision.<sup>115</sup> A misrepresentation about the requirement must be material to the government’s payment decision in order to be actionable.<sup>116</sup> Minor infractions in noncompliance with statutory, regulatory, or contractual requirements will not be considered material.<sup>117</sup>

*Escobar* rejected the expressly stated condition standard articulated in *Mikes*.<sup>118</sup> In *Mikes*, even though the court “agree[d] that the defendants certified they would comply with the terms on the form and that such compliance was a precondition of governmental payment,” it still denied the relator’s claims.<sup>119</sup> The court examined two different sections of the Medicare statute and found that the defendants certified compliance with the section that was a precondition of governmental payment, but their performance of spirometry test was governed by a separate Medicare section and this one, the one *Mikes* most heavily relied upon, was not an explicitly stated condition of payment.<sup>120</sup> *Escobar* rejected such labeling as dispositive.<sup>121</sup>

#### V. THE THEORY AFTER *ESCOBAR*

In the post-*Escobar* era, the government has contended that *Escobar* did not overturn the First and Ninth Circuits’ decisions.<sup>122</sup> Citing the language of the FCA, the government asserts that *Escobar* “reaffirmed” FCA jurisprudence that described “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property” and that “materiality is a flexible standard that can be met in a variety of circumstances.”<sup>123</sup> Lower courts have

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that the recipient of the representation attaches importance to the specific matter ‘in determining his choice of action,’ even though a reasonable person would not.”) (citing the RESTATEMENT (SECOND) OF TORTS §538, at 80).

<sup>115</sup> *Id.* at 2003 n.5.

<sup>116</sup> *Escobar*, 136 S. Ct. at 2003.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 1996.

<sup>119</sup> *Mikes v. Straus*, 274 F.3d 687, 698 (2d Cir. 2001).

<sup>120</sup> *Id.* at 699.

<sup>121</sup> *Escobar*, 136 S. Ct. at 2002.

<sup>122</sup> John Bentivoglio et al., *Escobar and the Implied Certification Theory: Initial Cases Raise the Bar on Materiality in False Claims Act Litigation*, SKADDEN, ARPS, SLATE, MEAGHER & FLOM (Nov. 7, 2016), <https://www.skadden.com/insights/publications/2016/11/emescobarem-and-the-implied-certification-theory-i>.

<sup>123</sup> Laurence Freedman, Samantha Kingsbury, & Karen Lovitch, *Supreme Court Decision on FCA Issues Leads to Brawl in Lower Courts*, MARTINDALE (Jan. 25, 2017), [http://www.martindale.com/health-care-law/article\\_Mintz-Levin-Cohn-Ferris-Glovsky-Pope-o-PC\\_2240026.htm](http://www.martindale.com/health-care-law/article_Mintz-Levin-Cohn-Ferris-Glovsky-Pope-o-PC_2240026.htm).

started to grapple with the materiality standard of *Escobar*. It is not surprising that there is no clear-cut answer as to what counts as a material misrepresentation under the FCA. *Escobar* should have done more to delineate what is needed to show that the misrepresentation would have affected the government's decision to pay.<sup>124</sup>

A. *The Winner Is . . .*

While *Escobar* has been seen as a win for the government and relators, the ruling's limitations created substantial hurdles for the government and relators to overcome and left defendants exposed to expansive discovery if the government and relators can get past the pleading stage. The materiality standard gained more teeth after *Escobar* as a result of the materiality factors. The "more rigorous materiality analysis" no longer considers whether a condition is expressly stated as dispositive; this announcement by the Court is an advantage for relators during the initial stages of a case. The Court emphasized that a complaint must allege "with plausibility and particularity" that the noncompliance was material to the government's decision to pay.<sup>125</sup> Before *Escobar*, materiality was rarely decided at the pleading stage.<sup>126</sup> If a *qui tam* relator or the government alleges in their complaint information and belief that a material condition was in fact violated; that the condition, whether expressly stated or not, was the *sine qua non* of the decision payment process; or if the relator can show information of where the payment has been denied in similar circumstances, then discovery will ensue. These are all factors that, before *Escobar*, were not clearly available to relators in showing materiality during the pleading stage.

It is not exactly clear who the winner is in *Escobar*. On one hand, the court rejected the *qui tam* relators' and the government's assertion, often used in false implied certification theory cases, that any claim for payment is material so long as the defendant knows that the government would be entitled to refuse payment if it was aware of the violation.<sup>127</sup>

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<sup>124</sup> See generally Joan H. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud that 'Counts' under the False Claims Act*, 2017 U. ILL. L. REV. 1811, 1811.

<sup>125</sup> *Escobar*, 136 S. Ct. at 2004 n.6; see also John Ruskusky & Emily Harlan, *Materiality Matters: The First Post-Escobar Decisions*, LAW360 (Jul. 18, 2016, 5:50 PM), <https://www.law360.com/articles/818294/materiality-matters-the-first-post-escobar-decisions> (making the argument that defendants have an advantage post-Escobar at pleading stage because several post-Escobar decisions have dismissed relators claims for failing to identify with sufficient particularity material falsehoods in the defendants claims).

<sup>126</sup> Tara Lee, *Could 'Escobar' Prove to Be This Term's Most Expensive Case?; Opinion: The U.S. Supreme Court OK'd Broad Parameters for Fraud Deserving of Penalties.*, NAT'L L. J. (July. 11, 2016), <http://www.nationallawjournal.com/id=1202762169591/Could-Escobar-Prove-to-Be-This-Terms-Most-Expensive-Case?slreturn=20170919183310>.

<sup>127</sup> *Escobar*, 136 S. Ct. at 1995.

And yet, the decision was a total defeat for Universal Health, because the Court held that, under certain circumstances, representations that result in half-truths can be actionable misrepresentations.<sup>128</sup> The Court emphasized that the FCA cases should not be used to settle ordinary contract disputes.<sup>129</sup> The Court was concerned that the FCA would be used as an avenue for the sort of run-of-the-mill cases that attempt to enforce noncompliance with regulations that have little to do with specific misrepresentations about the goods or services provided and more to do with contract disputes that have little effect on the government's decision to confer the benefit.<sup>130</sup>

Well before *Escobar*, critics opposed the false implied certification theory because they felt that relators and the government would use it as a bludgeon to exact harsh penalties for noncompliance with a wide range of regulations and contractual requirements instead of using the theory only for targeting fraud.<sup>131</sup> Nevertheless, after *Escobar*, the health care industry still has many of the same concerns, because the lower courts still differ in their application of the materiality standard.<sup>132</sup>

### B. Uphill Battle for Relators

After *Escobar*, courts are now more willing to consider materiality at the pleading stage.<sup>133</sup> The court in *United States ex rel. Lee v. Northern Adult Daily Health Care Center* granted, in part, a motion to dismiss in one of the first federal court cases to apply the materiality standard announced by *Escobar*. In doing so, it underscored the difficulty relators face in proving materiality. The relators failed to show *how* the defendants' noncompliance with Medicare regulations, (billing worthless claims), would have affected the government's decision to pay.<sup>134</sup> The

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<sup>128</sup> *Id.* at 2000.

<sup>129</sup> *Id.* at 2003 (explaining that FCA cases should not be an "all-purpose garden-variety tool to punish government contractors for contractual disputes).

<sup>130</sup> *Id.*

<sup>131</sup> *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) ("the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations").

<sup>132</sup> Evan Sweeney, *After Implied Cert Ruling, Courts Will Focus on 'Materiality'*, FIERCE HEALTHCARE (Jun. 21, 2016), <http://www.fiercehealthcare.com/antifraud/following-implied-certification-ruling-courts-will-focus-materiality> ("[W]histleblowers [will have] a stronger blueprint for successful FCA claims, and gives the government a reason to 'assert their resources' in FCA cases in which certain regulations are material to medical payments.").

<sup>133</sup> Bradley D. Wine et al., *Courts Are Taking Materiality Seriously Post-Escobar*, LAW360, (Sept. 20, 2016, 12:42 PM), <https://www.law360.com/articles/838782/courts-are-taking-materiality-seriously-post-escobar>.

<sup>134</sup> *United States v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 296 (E.D.N.Y. 2016) ("[B]ecause Relators have not alleged that noncompliance with [federal] regulations listed in the Amended Complaint would have influenced the government's decision to reimburse Northern Adult, Relators have not stated a claim under an implied false certification

relator's claims, which lacked particularity with regard to materiality, would have progressed under *Mikes* in the Second Circuit, but not after *Escobar*.<sup>135</sup>

However, Relators do not allege, as they are now required to do under *Universal Health*, that Northern Adult's misrepresentations were material and that the government would have refused reimbursement had it known of Northern Adult's noncompliance with Title VI and the cited DOH regulations. Instead, Relators argue that Northern Adult certified its compliance with regulations on which the government conditioned Medicaid reimbursement. While Relators' argument may have sufficed to support an implied false certification claim under the standard in *Mikes*, it no longer suffices under the standard in *Universal Health*.<sup>136</sup>

The Court in *Escobar* reemphasized that statutory, regulatory, and contractual requirements "are not automatically material, even if they are labeled conditions of payment."<sup>137</sup> Instead it regarded expressly stated conditions of payment as factors in determining materiality.<sup>138</sup> If the relators amend their complaint, given that they did not have the benefit of having the *Escobar* decision before them when they filed, they might be able to satisfy *Escobar*'s other condition—that the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes the specific representations misleading half-truths.<sup>139</sup>

#### i. *Escobar*'s Two-Part Test and Its First Condition

District courts are already split on whether fulfillment of the two-part test announced in *Escobar* is the only basis for the theory to attach. One of the two conditions of *Escobar* is that the claim for payment must make specific representations about the goods or services provided.<sup>140</sup> One court has already rejected the notion that "the two conditions [were] intended to describe the outer reaches of FCA liability: the Court stated that liability could be found "at least" where these conditions were satisfied.<sup>141</sup> Another court opined that the *Escobar* Court's "use of 'at least' indicated that it need not decide whether the implied false certification theory was viable in all cases, because the particular claim

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theory of liability.").

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> *Universal Health Servs. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016).

<sup>138</sup> *Id.*

<sup>139</sup> *N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d at 295.

<sup>140</sup> *Escobar*, 136 S. Ct. at 2001.

<sup>141</sup> *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1044-45 (C.D. Cal. 2016).

before it contained ‘specific representations’ that were ‘misleading half-truths.’”<sup>142</sup> With some courts finding the two-part test as an “exclusive means of establishing implied certification liability,” and other courts and the DOJ insisting that liability can attach without satisfying the first part of the test, whether or not defendants will find a favorable outcome depends on where the case is filed. For this reason, it seems *Escobar* changed very little for defendants and the risk faced depending on the circuit.

### C. Equally Uphill Battle for Defendants

#### i. Escobar’s Second Condition

The concern that there is an uphill battle for false-implied-certification-case defendants is a legitimate one, as two government contractors recently failed to survive a motion to dismiss with the Department of Energy.<sup>143</sup> The second *Escobar* condition was seen in *Williams v. City of Brockton* “when the party’s failure to disclose noncompliance with material statutory, regulatory or contractual requirements [amounted] to a misleading half-truth.”<sup>144</sup> The court drew direct parallels to *Escobar* in the misrepresentation of Brockton Police Department’s compliance with civil rights and anti-discrimination laws in order to obtain DOJ funding.<sup>145</sup> The court cited to *Escobar* in concluding that the police department’s misrepresentation was “neither minor nor insubstantial.”<sup>146</sup> Specifically, on the issue of materiality of Defendants’ alleged non-compliance with the non-supplanting requirements, the relator was unable to point to any statutes that underlie those requirements.<sup>147</sup> But, he was able to allege that the government has, on occasion, barred enforcement agencies from receiving grants because those agencies violated the non-supplanting requirements.<sup>148</sup> Therefore, the alleged conduct was sufficient to show that “the Government

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<sup>142</sup> *Rose v. Stephens Inst.*, No. 09-cv-05966-PJH, 2016 WL 6393513, at \* 5 (N.D. Cal. Oct. 28, 2016).

<sup>143</sup> *United States v. Savannah River Nuclear Solutions, LLC*, No. 1:16-cv-00825-JMC, 2016 U.S. Dist. LEXIS 168067, at \*88 (D.S.C Dec. 6, 2016); *see also* *Johnson et al. v. Golden Gate National Senior Care L.L.C.*, 223 F. Supp. 3d 882, 894 (D. Minn. 2016) (“[But] the distinction between conditions of payment and conditions of participation are not dispositive of the FCA’s materiality requirement [and a] fact-intensive inquiry is needed before determining materiality.”).

<sup>144</sup> *United States ex. rel Williams v. City of Brockton*, No. 12-cv-12193-IT, 2016 U.S. Dist. LEXIS 178032, at \* 21 (D. Mass. Dec. 23, 2016) (quoting *Escobar*, 136 S. Ct. at 2001).

<sup>145</sup> *Id.* at \*13.

<sup>146</sup> *Id.* at \*20.

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

consistently refuse[d] to pay claims in the mine run of cases based on noncompliance” with the non-supplanting requirements.<sup>149</sup> Additionally, as seen in *Escobar*, the relator relied on the Escobarian “essence of the bargain” factor stating the grantee’s compliance with federal civil rights laws “go[es] to the very essence of the bargain” of the government’s decision to provide funding.<sup>150</sup> The court agreed, stating the “centrality of racially-neutral and non-discriminatory policing to the COPS program is strong evidence that a grantee’s non-compliance would have the tendency to influence the DOJ’s decision to award the grant.”<sup>151</sup>

The court denied pharmaceutical giant Celgene’s summary judgment motion against the relator’s claims that Celgene was involved in an unlawful campaign to promote off-label promotion of two of its drugs and payment of illegal kickbacks to physicians.<sup>152</sup> The DOJ argued that “the fact that the government may continue to pay even after discovering wrongdoing does not establish a lack of materiality[;] [t]he government may wish to avoid further cost or simply wish to afford an accused party the opportunity to be heard in court.”<sup>153</sup>

Notwithstanding the DOJ’s arguments, the U.S. District Court for the Central District of California found that genuine dispute of material fact existed as to whether Celgene’s claims were material to Medicare and the government’s payment decision-making process.<sup>154</sup> Specifically, the court held that even if CMS knew that the claims were not for prescription drugs covered by Medicare Part D, and therefore failed to meet the medical acceptance requirement, it does not mean that CMS had “actual knowledge” that the claims were non-compliant and proceeded to reimburse the claims.<sup>155</sup> An important takeaway from *Escobar* is the focus on the government’s knowledge of noncompliance and how this relates to materiality.

The Eighth Circuit issued one of the first post-*Escobar* opinions to deal with materiality in *United States ex rel. Miller v. Weston Educational*.<sup>156</sup> The relators, former employees, claimed that Heritage, a for-profit college, signed a Program Participation Agreement (“PPA”) with the Department of Education (“DOE”) to receive funds under Title

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<sup>149</sup> *Id.* at \*20.

<sup>150</sup> *City of Brockton*, 2016 U.S. Dist. LEXIS 178032, at \*18.

<sup>151</sup> *Id.*

<sup>152</sup> *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1036 (C.D. Cal. 2016).

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 1037.

<sup>155</sup> *Id.*

<sup>156</sup> *U.S. ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494 (8th Cir. 2016).

IV of the Higher Education Act of 1965.<sup>157</sup> Once the PPA was in place, the relators alleged that Heritage employees falsified grades and attendance records without the instructors' consent to induce the DOE to provide funds.<sup>158</sup> The district court granted summary judgment on all claims and held that Heritage did not promise to keep perfect records.<sup>159</sup> Further, it found that "any promise was not material to the disbursement of funds."<sup>160</sup> The Eighth Circuit found that the lower court erred in granting summary judgment because "a reasonable jury could find that the college knew it had to keep accurate grade and attendance records and intended not to do so." Additionally, the college's promise to keep adequate records was material to the government's disbursement decisions because "the college could not have executed the Program Participation Agreement (PPA) with the DOE without stating it would maintain adequate records and, without the PPA, the college could not have received any Title IV funds."<sup>161</sup> The Supreme Court granted certiorari and vacated the Eighth Circuit's decision with orders to reexamine its prior holding in light of *Escobar*, which had been decided after the Eighth Circuit vacated the district court's decision. On remand, the Eighth Circuit once again reversed the grant of summary judgment, as there was a triable question of fact and a legitimate dispute about whether Heritage intended to falsify student grades and break its promise to keep accurate records under the PPA.<sup>162</sup> Again, the court found that the recordkeeping requirement was material because it was a condition of payment and, even though such a label is not dispositive, it is an *Escobar* factor nonetheless.<sup>163</sup> Specifically, in keeping with *Escobar*, the Eighth Circuit reiterated that a false statement is material if a reasonable person would likely attach importance to it, or the defendant knew or should have known that the government would attach importance to it.<sup>164</sup>

The court rightfully found that Heritage's promise was material

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<sup>157</sup> *Id.* at 498.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* at 499.

<sup>160</sup> *Id.*

<sup>161</sup> United States ex rel. Miller v. Weston Educ., Inc., 784 F.3d 1198, 2016 (8th Cir. 2015), vacated, 136 S. Ct. 2505 (2016).

<sup>162</sup> *U.S. ex rel. Miller*, 840 F.3d at 503.

<sup>163</sup> *Id.* at 504 ("In order to be for Title IV an institution 'shall' enter into a PPA that 'shall condition the initial and continuing eligibility of an institution to participate in a program upon compliance with' certain requirements, including that the 'institution will establish and maintain such administrative and fiscal procedures and records as may be necessary to ensure proper and efficient administration of funds.'") (citing 20 U.S.C. § 1094(a)) (emphasis added).

<sup>164</sup> *Id.* at 503 (reiterating *Escobar*'s materiality standard); see also *Universal Health Servs. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016).

because a reasonable person would attach significant importance to a promise to keep records that are “necessary to ensure funds go where they are supposed to go.”<sup>165</sup> The recordkeeping requirement was found as a condition of payment in three different sources of law: statute, regulation, and the PPA signed by Heritage. Lastly, and most notably in light of the *Escobar* factors, the court said the “government’s acts confirm that it cares about the promise at issue” and relies on the school to keep accurate records to monitor regulatory compliance.<sup>166</sup> Pointedly, and perhaps most striking of the relators’ claims in light of *Escobar*, is that the DOE sometimes “terminates otherwise eligible institutions for falsifying student attendance and grade records.”<sup>167</sup> Therefore, had the government known of the fraudulent recordkeeping practices at Heritage, given the importance the government attaches to maintaining accurate records as shown in Title IV of the Higher Education Act of 1965 and the PPA itself, the government would have terminated funding.<sup>168</sup>

#### D. Still Good Law?

During the pre-*Escobar* era, defendants in civil cases within the Fourth Circuit, D.C. Circuit, or First Circuit faced more risk where the theory was applied broadly. According to the government, those cases are still good law. In *United States ex rel. Mateski v. Raytheon Co*, the DOJ asserted in its *Statement of Interest* that the Supreme Court “left intact the Ninth Circuit’s prior case law addressing this very question” of implied certification liability.<sup>169</sup> Conversely, some courts have already asserted that *Escobar* may overturn long-standing precedent. Recently, for example, the court in *Rose v. Stephens Institute* found that *Escobar* did not alter Ninth Circuit materiality precedent set forth in *United States ex rel. Hendow v. University of Phoenix*.<sup>170</sup> The defendant in *Hendow* argued that the alleged noncompliance was a condition of participation and not a condition of payment and, therefore, was not material and could not form a basis for an FCA claim under *Mikes*.<sup>171</sup> The court disagreed and reasoned that the participation-payment

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<sup>165</sup> *U.S. ex rel. Miller*, 840 F.3d at 504.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at 505.

<sup>168</sup> *Id.*

<sup>169</sup> Paul F. Khoury, Ralph J. Caccia, & Shane B. Kelly, *Government Contractors Deal with the Uncertain Shadow of Universal Health Services, Inc. v. United States Ex Rel. Escobar*, 52-SPG PROCUREMENT LAWYER 12, 12-13 (2017) (stating that the Supreme Court left Ninth Circuit’s prior case law addressing the very question of implied certification liability intact).

<sup>170</sup> *Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1173 (9th Cir. 2006).

<sup>171</sup> *Id.* at 1176.

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differentiation found in *Mikes* was limited to the Medicare context and that, “[i]n the context of Title IV and the Higher Education Act, if we held that conditions of participation were not conditions of payment there would be no conditions of payment at all.”<sup>172</sup> Further, the court found that precedent in the Ninth Circuit, following *Ebeid v. Lungwitz*, did not contain “the expressly stated conditions” limitation.<sup>173</sup>

Even still, the *Rose* court certified three questions of law for interlocutory appeal to decide whether the Ninth Circuit’s precedent was still good law because “[the] case [was] a strong vehicle for the Ninth Circuit to consider its materiality law in light of *Escobar*, as the facts are substantially similar to those in *Hendow*.”<sup>174</sup> Since the reasoning of *Hendow* relied on the fact that Title IV funds are “explicitly conditioned,” and *Escobar* made clear that labels are not dispositive, the court asked “does *Hendow*’s holding that the ICB is material under the FCA remain good law after *Escobar*?”<sup>175</sup> The *Rose* court noted that in certifying the questions it would decide amongst a split in the courts on whether the two-part test must always be satisfied for implied false certification liability under the FCA, or the Ninth Circuit *Ebeid*’s test for implied false certification remained good law.<sup>176</sup>

#### *E. The Benefit of Hindsight – Pre-Escobar Cases Now*

The debate over whether a court should look to the condition of participation standard used in *Ab-Tech* and again by the Eleventh Circuit, or the condition of payment standard in *Mikes* did not amount to “a distinction without a difference.”<sup>177</sup> Defendants were treated more favorably in the Second Circuit and the circuits that followed its standard. The reason why the *Hendow* court stated that the distinction may amount

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<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *But see* Order Granting in Part Motion to Certify Order for Interlocutory Appeal at 4-6, *United States ex rel. Rose v. Stephens Inst. d/b/a Acad. of Art Univ.*, No. 4:09-cv-05966-PJH (N.D. Cal. July 25, 2016) (ECF No. 219).

<sup>175</sup> *Rose v. Stephens Inst.*, No. 09-cv-05966-PJH, 2016 WL 6393513, at \* 12 (N.D. Cal. Oct. 28, 2016); *see also* *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1175 (9th Cir. 2006).

<sup>176</sup> *Rose*, 2016 WL 6393513, at \*10.

<sup>177</sup> Brief for the Taxpayers against Fraud Education Fund As Amici Curiae Supporting Appellants and Reversal

at 10, *United States ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103 (1st Cir. 2016) (No. 14-1423) (citing *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006)); *see also* *U.S. ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1222 (10th Cir. 2008) (explaining that some regulations or statutes may be so integral to the government’s payment decision as to make any divide between conditions of participation and conditions of payment a “distinction without a difference”).

to “distinction without a difference” is because some regulations or statutes may be so integral to the government’s payment decision as to make any divide between conditions of participation and conditions of payment necessarily intertwined.

To see why this is so, one only need look at the University’s semantic argument, in which it claims that for a condition of participation, an institution says it “*will*” comply with various statutes and regulations, but for a condition of payment, an institution says that it ‘*has* complied.’ This grammatical haecceitosis is unmoored in the law and it is undercut by the Program Participation Agreement itself. In the section that the University concedes contains conditions of payment—the section entitled ‘Certifications Required From Institutions’—the University agrees that it ‘will’ or ‘shall’ comply with various regulations no less than six times. Under the University’s logic, these future-tense assertions could not be conditions of payment, and yet it concedes that they are. Its concession is correct: these, and all other promises to comply with the Program Participation Agreement are conditions of payment. These conditions are also ‘prerequisites,’ and ‘the *sine qua non*’ of federal funding, for one basic reason: if the University had not agreed to comply with them, it would not have gotten paid.<sup>178</sup>

Today, after *Escobar*, *Hendow* would have been decided the same because the defendant’s compliance goes to the “essence of the bargain.”

The *Escobar* Court’s treatment of *Mikes* and the “expressly stated conditions” standard helps relators and the government, as the absence of an expressly stated condition does not necessarily prove that the condition is not material. *Mikes*, perhaps, would have been decided differently after *Escobar*, if *Mikes* could have shown that the qualitative standard of care mandate of the Social Security Act was essential to the bargain in receiving reimbursement. The *Mikes* Court was more concerned with preventing the use of the theory where the “quality of care failed to meet medical standards[,] [which] would promote federalization of medical malpractice.”<sup>179</sup> Had *Mikes* been able to prove that the defendants’ performance of spirometry was unnecessary, she would have succeeded because, pursuant to § 1395(y)(a)(1)(A), the Secretary of Health and Human Services prohibits “payment of benefits for any experimental, investigational, or unproven treatment or diagnostic method not yet generally accepted in the medical profession.” The correlation between the medically necessary spirometry tests and this Medicare regulation are the *Escobarian* “*sine qua non*” of government payment—not the quality of the spirometry tests.

Without *Escobar*, in the Second Circuit and the circuits that

<sup>178</sup> *Hendow*, 461 F.3d at 1176.

<sup>179</sup> *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001).

followed *Mikes*, a contractor could have submitted a claim for payment that is related to the *sine qua non* of government payment but, because the condition was not an expressly stated condition of payment, liability did not attach. The government was duped and paid for a fraudulent claim, albeit not an expressly stated condition. This runs counter to Congressional intent, in particular after the False Claims Amendments Act of 1986.<sup>180</sup>

Out of all of the factors the *Escobar* Court urged the lower courts to look at in finding materiality, evidence that the misrepresentation goes to the “essence of the bargain” should be given the most weight. *Escobar’s* “very essence of the bargain” factor was seen in the Ninth Circuit recently.<sup>181</sup> Relators, former employees, Health Choice Arizona, a subsidiary of IASIS Healthcare LLC, a prepaid Medicaid-managed health plan that contracts with Arizona Health Care Cost Containment System, succeeded in showing the materiality of an implied false certification claim.<sup>182</sup> The relators were able to establish materiality at the pleading stage because the contractual requirements that the plan allegedly failed to meet—such as “all funds be both medically necessary and cost-effective—were the *sine qua non* of government payment.<sup>183</sup> This requirement was absolutely necessary for the relationship between the government and its decision to pay and the health care providers.<sup>184</sup> This *Escobarian* factor is the strongest of all the factors in proving materiality.

Evidence that shows that a defendant knows that the government routinely denies payment based on noncompliance with the particular requirement in addition to the government knowledge bar, should not be given as much weight as the others, because it puts an enormous burden on the government to “change its position” after knowledge of noncompliance. The government may have a particular reason for

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<sup>180</sup> S. Rep. No. 99-345, at 3 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5269 (“explaining that restrictive interpretations of the act’s liability standard, burden of proof, qui tam jurisdiction and other provisions in order to make the False Claims Act a more effective weapon against Government fraud.”); see also *Universal Health Servs. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2001-02 (2016) (“A defendant can have ‘actual knowledge’ that a condition is material without the Government expressly calling it a condition of payment. If the Government fails to specify that guns it orders must actually shoot, but the defendant knows that the Government routinely rescinds contracts if the guns do not shoot, the defendant has ‘actual knowledge.’ Likewise, because a reasonable person would realize the imperative of a functioning firearm, a defendant’s failure to appreciate the materiality of that condition would amount to ‘deliberate ignorance’ or ‘reckless disregard’ of the truth or falsity of the information even if the Government did not spell this out.”).

<sup>181</sup> *United States ex rel. Fisher v. IASIS Healthcare LLC*, No. CV-15-00872-PHX-JJT, 2016 U.S. Dist. LEXIS 155517, at \*49 (D. Ariz. Nov. 8, 2016).

<sup>182</sup> *Id.* at \*49-50.

<sup>183</sup> *Id.* at \*49.

<sup>184</sup> *Id.* at \*50.

continuing payment such as public health or safety.<sup>185</sup> This should not contradict materiality. It should not refute noncompliance and fraud committed by the contractor.

The *Escobar* court supports the original intent of the FCA to combat knowing intent to commit fraud and not minor or technical violations of conditions of participation such as not meeting the adequate standard of care. Most striking about the post-*Escobar* landscape is the idea that the government considers *Escobar* a victory. Yet, industry stakeholders hope that the materiality standard will be a difficult bar for whistleblowers and the government to meet. The different perspectives on *Escobar's* consequences will likely dissipate once a trend develops in determining what kinds of misrepresentations likely influenced the payment-making process of the government.

#### IV. CONCLUSION

A holistic approach to finding materiality is the correct one. *Escobar's* call for a demanding, fact-intensive inquiry into whether a contractor's misrepresentation actually affected or likely would have affected the government's decision to pay is well balanced. It does not rush to impose dispositive labels as seen in *Mikes*, or cast a wide net of liability around standard of care violations. It seems completely fair to require relators to not only show that the government would have had the option of denying payment had it known of the noncompliance, but also show why the government would have denied payment. That said, contractors have been put on notice that, while it is not so easy to prove materiality, the theory is certainly alive.

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<sup>185</sup> See *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 614 (2d Cir. 2016).